

PATENT  
Attorney Docket No. 8123.003.US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

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AUG 03 2006

In re Application of: )  
William A. KNAUS and Richard D. MARKS ) Group Art Unit: 3626  
Application Number: 09/822,261 ) Examiner: Lena Najarian  
Filed: April 2, 2001 )  
For: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND  
MANAGEMENT OF MEDICAL RECORDS

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

ATTN: MAIL STOP AFTER FINAL

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets.

In the event additional fees are necessary, please charge such fees to the undersigned's Deposit Account No. 14-1437.

Respectfully submitted,

NOVAK DRUCE &amp; QUIGG LLP

Date: August 3, 2006

By:   
James Remenick  
Registration No. 36,902

Customer No. 28694  
Novak, Druce & Quigg LLP  
1300 Eye Street, N.W.  
400 East Tower  
Washington, DC 20005  
Telephone: (202) 659-0100  
Facsimile: (202) 659-0105

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wm. A. KNAUS &amp; Richard D. MARKS

Application Number: 09/822,261

Filed: April 2, 2001

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND  
MANAGEMENT OF MEDICAL RECORDS

Group Art Unit: 3626

Examiner: Lena A. Najarian

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United States Patent and Trademark Office  
P.O. Box 1450  
Arlington, Virginia 22313-1450

Dear Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant respectfully requests the United States Patent and Trademark Office ("PTO") to review the rejections set forth in the final Office Action, mail dated March 3, 2006.

I. Brief Prosecution History

Applicant received a non-final Office Action, mail dated August 1, 2005, wherein applicant's claims stood rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden (U.S. Patent Application No. 2002/0026332; "Snowden") in view of Shepard (U.S. Patent No. 6,026,363), and further in view of Baker (PCASSO), Malik (US Patent Application No. 2001/0037219; "Malik") or Shear (U.S. Patent No. 4,827,508).

In this Office Action, the Examiner re-interpreted many elements of the claimed invention. Applicant responded, traversing each rejection and the Examiner's re-interpretations as improper and internally inconsistent. Applicant also furnished an affidavit under 37 C.F.R. § 1.131 with supporting evidence (the "Affidavit"). Under M.P.E.P. § 715, the Affidavit demonstrates that, prior to both Snowden's and Malik's filing dates, the inventors had conceived and/or reduced to practice the elements of the claimed invention actually found in Snowden and Malik. Therefore, if the Examiner agreed that her re-interpretations were incorrect, the rejections would be withdrawn. However, if the Examiner refused, the Affidavit renders the rejections moot.

The Examiner next issued a final Office Action mail dated March 2, 2006, reasserting the same rejections. No rejections were reconsidered and the Examiner refused to modify her reinterpretation of the claims. The Examiner now asserted that Applicant's Affidavit failed to demonstrate conception and/or reduction to practice "of the whole invention claimed or something falling within the claims" (final Office Action, page 15), because she was unable to locate applicant's *entire* invention in the Affidavit, and because Applicant failed to show a nexus between the Affidavit and the claimed invention. Because the Examiner's analysis contains material errors, including violation of the MPEP, reconsideration is appropriate.

II. The Claim Element of "Nonrepudiation"

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Nonrepudiation is positively recited as an element of Applicant's claimed invention (e.g., claims 1, 8-10, 26, 46, 63, 65, 70 and 71). In claim 1, medical information contained within medical records is verified as accurate and correct such that: *"one or more records of the collection possess a characteristic of non-repudiation."* This element is also clear from the specification: *"Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon"* (specification, page 17, lines 14-17). This claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and the plain meaning of this term in the claims.

The Examiner admits that: "Snowden does not expressly disclose one or more medical records of the collection posses a characteristic of non-repudiation such that the medical information contained within said medical records is verified as to accuracy or transcription and certified for accuracy of transcription." (see non-final Office Action, page 6). Applicant interprets this statement to mean that Snowden does not disclose or suggest non-repudiation as claimed by Applicant.

### **III. The Claim Element of "Certification"**

Certification is positively recited as an element of Applicant's claimed invention (e.g., claims 1, 11, 21-23, 63, 65, 72 and 73). In claim 1, the invention comprises a collection of medical records such that "medical information contained within said medical records is verified as to accuracy and certified for accuracy." Applicant states: *"The invention may include a form of medical record that can be completed at one of a plurality of certification levels"* (specification, page 15, lines 12-13). *"Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered ...."* (specification, page 15, lines 22-25; and claims 20, 37, 43). This claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and plain meaning of this term in the claims.

The Examiner admits that: "Snowden does not expressly disclose one or more medical records of the collection posses a characteristic of non-repudiation such that the medical information contained within said medical records is verified as to accuracy or transcription and certified for accuracy of transcription." (see non-final Office Action, page 6). Applicant interprets this statement to mean that Snowden does not disclose or suggest Certification as claimed by Applicant.

### **IV. Shepard Teaches away from the Claimed Invention**

Shepard does not disclose or suggest at least the elements of "certification of medical records" (claims 1, 11, 21-23, 63, 65, 72 and 73) or "nonrepudiation of medical records" (claims 1, 8-10, 26, 46, 63, 65, 70 and 71) as these elements are claimed by Applicant, and, in fact, teaches away from Applicant's claims. The Examiner's re-interpretation of these elements by distorting claim terms to shoe-horn them into portions of Shepard is both hindsight and improper under the MPEP.

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Shepard is not combinable with Snowden and would not lead one skilled in the art toward applicant's invention. Applicant's claimed invention is directed to patient-based records. Shepard is directed to the conventional hospital-based or physician-office system, or, in other words, to a source-centered record system, which leads one skilled in the art in exactly the wrong direction. As stated in Applicant's specification: "*Integration of medical information is patient-centered, not source- or physician-centered....*" (emphasis added) (specification, page 7, lines 16-17). A "teaching away," as we have here, is the strongest indication of the non-obviousness of applicant's claimed invention.

The Shepard medical record management system is directed to physician- or a hospital-based records system. In Shepard, an advantage of the invention is that medical records are to be recorded by a "*medical history documentation system [that] uses a second person who functions as the recorder and is present during the physical examination and/or treatment by the first person who is the health care professional*" (emphasis added) (see Shepard, column 6, lines 52-57). Shepard states that the recorder of the medical information prepares a Report Form for review by the examining physician before that physician verifies and signs the report (Shepard, column 11, lines 58-67). Only then is it considered a "Final Report Form" suitable for placing in the patient's hospital or office medical record. Thus, Shepard's records would be verified as correct only by the health care professional who conducted the examination. This is not a patient-based record system as described in the instant application, but a conventional hospital-based record system for creating original medical records.

Further, Shepard claims no vetting or certification according to applicant's claimed invention. The parts of Sheppard alleged in the Office Action to disclose or suggest vetting and/or certification are column 1, lines 29-37; column 4, line 60 to column 5, line 11; column 5, lines 58-62; column 6, lines 8-13; column 8, lines 44-48; column 12, lines 8-12; column 13, line 54 to column 14, line 9; and column 14, lines 61-65. None of these sections discloses or suggests vetting or certification according to applicant's claimed invention. All the instances noted in Shepard refer to verification of the patient's record by the physician or health care worker who is tasked by the source with creating the record in the first place. Shepard describes delegating the task of actually writing the medical record to another person employed by the source office or hospital and yet who is not administering the care. The recorder is, for example, to be present in the room when the patient is being examined by the physician (Shepard, column 6, lines 52-57). Once drafted by the recorder, the draft record is provided to the source-employed care-giver, most typically the physician, for final review before it becomes a part of the patient's institutional medical record. Thus, although Shepard may describe a system to create "original" source medical records, Shepard neither discloses nor suggests vetting or certification according to applicant's claimed invention. This highlights another aspect of applicant's claimed invention, which is recited in claim 20, and clearly distinguishes the instant claims from Shepard.

With reference to instant claim 20, and in contrast to the Examiner's allegation, the information contained within Shepard's source medical records cannot be better than exists at the source from which the record was obtained. This is at least because the hospital, physician or health care worker "is" the source of the record. In other words, the Shepard system only envisions creating original medical records at the source. Therefore, Shepard can

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not logically be a system of creating medical record that are "better" than exist at the source from which the records were originally obtained (i.e. better than the original record).

For at least these reasons, Shepard clearly teaches away from applicant's claimed invention and Applicant respectfully requests that all rejections based on Shepard be withdrawn for failure to disclose Applicant's claimed invention and for failure to establish a *prima facie* case of obviousness.

**V. The Examiner's Requirement that Applicant's Affidavit Disclose the Entire Invention as Claimed in the Application is Contrary to the MPEP**

The Examiner's also erroneously asserts that Applicant must state the entirety of its claimed invention in the Affidavit for the Affidavit to be considered sufficient (final Office Action, pages 5-6). This is incorrect. As stated in MPEP § 715.02, Applicant only needs to show that the Affidavit contains the elements of the claimed invention that are found in the supposed prior art:

*[A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient....(Emphasis added.)*

The Examiner's analytical approach to Applicant's Affidavit is contrary to the MPEP, and thus clear error. Both Snowden and Malik should be removed as prior art references in view of Applicant's Affidavit. Further, because the Examiner provided no comments regarding Malik and Applicant's Affidavit, Malik at least should be removed as a prior art reference and all claims rejected over Malik be declared allowable.

**VI. Applicant's Invention is Disclosed in the Affidavit**

In the Office Action the Examiner states that she was unable to locate "the whole invention claimed or something falling within the claims" within the Affidavit (final Office Action, page 5). Erroneously, the Examiner focuses her review on disclosures in the Affidavit that are allegedly *absent* from Applicant's claims:

"To the extent the Examiner understands the submitted materials, the Brief Background and Rationale section of the document at page 4 makes references to elements not present in any of the recited claims, namely, that the "patient would be the main repository" and "carry" the results with them to all medical encounters." (final Office Action, pages 5-6).

Instead, the affidavit discloses a broadband (Internet-based), secure repository for the "accurate" storage of patients' medical record data. This invention is wholly sufficient to swear behind Snowden.

The Examiner improperly analyzed Applicant's Affidavit and so mischaracterized many aspects of the Affidavit relevant to the instant claims. Clearly the Examiner analyzed the instant claims using one interpretation of the claim elements and then analyzed the Affidavit using a mutually exclusive interpretation. Under the MPEP, the Examiner cannot arbitrarily redefine "certification" and "nonrepudiation" one way in part of her analysis, and then revert to a different, mutually exclusive, set of definitions in another part. Either the rejections are erroneous or Applicant's Affidavit is sufficient to swear behind both Snowden and Malik. One way or the other, allowance is compelled.

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**VII. There is "No" Nexus Requirement in 37 C.F.R. § 1.131**

The Examiner stated (multiple times including during the Interview of October 20, 2005) that Applicant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15). This is clear error. A "nexus" between an Affidavit and a claimed invention is required only under 37 C.F.R. § 1.132, not 37 C.F.R. § 1.131.

**VIII. The Examiner's Requirements for the Affidavit are Unsupported in the MPEP**

In the Advisory Action, the Examiner asserts that Applicant's Affidavit fails to show sufficiently that the invention "as claimed" was completed prior to the date of the applied references, referencing MPEP § 2138.05. MPEP § 2138.05 to a discussion of the definition of the phrase, "reduction to practice." This is not the standard of review for an Affidavit. Under MPEP § 715.02, Applicant need only show that the Affidavit contains the *elements* of the claimed invention found in the supposed prior art. It would be sufficient if Applicant reduced none of the claimed invention to practice, provided applicant had possession of the *elements* of the claimed invention alleged to be in the supposed prior art. Further, that Affidavit evidence must be clear to those of ordinary skill in the art (see, e.g., MPEP 715.02), and Applicant's Affidavit fully meets that standard.

**IX. The Examiner's Failure to Review Claim 20 is Error**

In neither the non-final nor the final Office Action did the Examiner ever review certain claims. For example, there is no disclosure in any of the cited references relating to claim 20 with regard to the element: "accuracy and correctness of said at least one medical record is better than exists at the source site from which the medical record was obtained." None of the cited references, nor any comments by the Examiner, discloses or suggests a computer-networked system wherein the medical records are *more* accurate than the records collected from the source sites where the records originated. At least this claim should be immediately declared allowable.

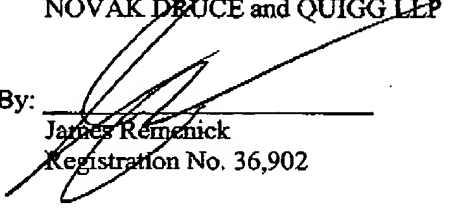
**Conclusion**

For at least these reasons, Applicant respectfully requests withdrawal of all rejections in the final Office Action, including all prior art rejections based on Snowden and Malik, and the prompt issuance of a Notice of Allowance.

In the event that any additional fees are deemed necessary with the filing of this Request, the Commissioner is authorized to charge those fees to the undersigned's Deposit Account No. 14-1437, referencing Attorney Docket No. 8123.003.US.

Date: August 3, 2006  
Customer No. 28694  
Novak Druce and Quigg LLP  
1300 Eye Street, NW, 400 East Tower  
Washington, DC 20005  
Telephone: (202) 659-0100  
Facsimile: (202) 659-0105

Respectfully submitted,  
NOVAK DRUCE and QUIGG LLP

By:   
James Remenick  
Registration No. 36,902